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December 12, 2002

Dockets Management Branch
(HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: Docket No. 94P-0036 – Food Labeling: *Trans* Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims; Reopening of the Comment Period

Dear Sir or Madam:

The American Dairy Products Institute (ADPI) hereby responds to the referenced request for comments on proposed regulations governing *Trans* Fatty Acid nutrition information disclosure. ADPI, headquartered in Chicago, is the trade association of the nation's leading manufacturers and processors of processed dairy products, including whey and modified whey products, nonfat dry milk, evaporated milk, lactose, and other nutritious and functional dairy ingredients.

SUMMARY

ADPI strongly opposes the proposed use of the footnote statement "Intake of *trans* fat should be as low as possible" and the corresponding asterisk that would appear in the percent Daily Value column of the Nutrition Facts panel. For the reasons discussed below, ADPI believes that the precedent established by the proposed footnote would be bad for the food industry, and, more important, misleading and confusing to consumers.

ADPI COMMENTS

1. The Proposed Footnote Statement Establishes a Bad Precedent.

FDA's acknowledged rationale for recommending minimal consumption of trans fat is the report recently issued by the Institute of Medicine/National Academy of Sciences (IOM/NAS). Yet, we believe that the proposed footnote represents a distinct reversal of FDA nutrition labeling policy, which favors neutral disclosure of nutrition information so as to allow the consumer to make an informed decision on how a food fits into his or her total diet. Instead, the proposal amounts to a warning statement about a particular food component, irrespective of its role in the total diet.

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The warning statement sets a precedent for required disclosures relating to nutrients that regulators may believe to be unhealthy in and of themselves. Indeed, it implies that trans fat may be more unhealthy than other nutrients, *e.g.*, saturated fat. Although FDA states in the proposed rule that it has insufficient data to establish a Daily Value for trans fat, the proposed warning statement suggests that the Daily Value is zero, and that the tolerable upper intake level (UL) is also zero. However, the IOM/NAS report clearly states that a UL of zero would be inappropriate:

[B]because *trans* are unavoidable in ordinary, non-vegan diets, consuming zero percent of energy would require significant changes in patterns of dietary intake.

Accordingly, the proposed footnote is at odds with FDA policy and would not accurately communicate the government's position on trans fat.

2. The Proposed Footnote Statement Would be Misleading to Consumers.

The proposed warning statement is likely to mislead and confuse consumers. The statement suggests that trans fat is more harmful than saturated fat for which FDA has established a Daily Value. When incorporated into the existing Nutrition Facts panel, the warning statement is likely to lead consumers to believe that trans fat should be avoided entirely, while there is an acceptable level of saturated fat. Clearly this is not the intent of the proposal.

In addition, consumers have no frame of reference for understanding what FDA means by "as low as possible," a phrase that could have several interpretations. Particularly in the context of the Nutrition Facts panel, where there are likely to be higher numbers listed for other nutrients, *e.g.*, total fat and carbohydrates, the phrase "as low as possible" does not provide consumers with any quantitative information for deciding exactly what level of trans fat would be acceptable.

Finally, if consumers do attempt to avoid trans fat entirely, adverse dietary effects could result, as noted by the NAS/IOM Panel:

[s]uch adjustments may introduce undesirable effects (*e.g.*; elimination of commercially prepared foods, dairy products and meats that contain trans fatty acids, may result in inadequate intakes of protein and other micronutrients) and unknown unquantifiable health risks.

The NAS/IOM panel obviously never thought it prudent or realistic that Americans alter their diets to altogether avoid the consumption of trans fat.

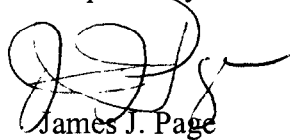
3. ADPI Supports Straightforward and Nonmisleading Trans Fat Labeling.

Instead of the proposed warning statement and asterisk in the percent Daily Value column, ADPI believes that FDA should simply require the amount of trans fat to be objectively declared, leaving the Percent Daily Value column blank. An alternative approach would be to include an asterisk in the percent Daily Value column with a corresponding footnote that states "Daily Value not established." This type of labeling would be consistent with the Agency's requirements for labeling other nutrients that lack a Daily Value.

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ADPI appreciates the opportunity to comment on these important issues. We stand ready to respond to any questions that the Agency may have.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "James J. Page", is written over the typed name.

James J. Page
Chief Executive Officer

JJP/bk